

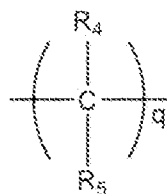
REMARKS

The office action issued by the Examiner and the citations referred to in the office action have been carefully considered.

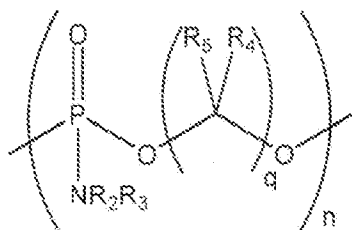
Constructive Election

The election imposed by the Examiner is respectfully traversed according to the following arguments. The Examiner alleges that "newly submitted claims 28-32 are directed to an invention that is independent or distinct from the invention originally claimed" because "the claims are not readable on the elected inventions and are not from the original claims after the restriction."

The Applicants respectfully disagree. Claim 28 is exactly claim 6 rewritten as an independent claim. The dependent claims that follow mirror claims 2-5. Examiner should note that the difference between claim 1 and claim 6 is the R_1 with:



The above molecule, when substituted into formula 1 yields the following molecule:



It is respectfully submitted that claim 28 is simply a narrowed version of claim 1. More importantly, if the Examiner will kindly reconsider, he will find that claims 28-32 indeed are readable on the elected inventions that stemmed from the original claims after the first restriction.

Importantly, the Examiner should further note that claim 28 does not read on the '581 patent cited against this application because the polymer structure is not the same (i.e., R_1 of the instant application is not selected from group of R' molecules of the '581 patent listed in Col. 4, line 32 to Col. 5, line 4).

Claim Rejection § 112

The Examiner alleges that amended claim 1 is non-enabled. The Applicants respectfully disagree for two reasons. First, amended claim 1, even with the negative limitation, is a subset of the original genus claimed in claim 1. Original claim 1 was enabled by the specification. Amended claim 1 is a subset of original claim 1 and is therefore enabled by the specification as well.

Second, direct support for the claimed species are found in the specification as recited in the last Office Action Response submitted by the bc Application, namely in paragraphs [0042] *et seq.* Additional support is located in Figs. 1 and 3, which recite specific species that are encompassed in amended claim. Finally, specific structure P5-SP, P5-BA, P5-DMA, P5-DEA, and P5-TMA are discussed in depth in Examples 1 to 6. The applicant kindly asks the Examiner to please withdraw the Claim Rejection under § 112 for the above discussed reasons.

Claim Rejections §§ 102(b) and 103(a)

Claims 1-6 stand rejected over U.S. Patent No. 5,194,581 under 35 U.S.C. §§ 102(b) and 103(a).

A. Anticipation Rejection

As the Examiner is undoubtedly aware, MPEP § 2131.02 provides examination guidance with respect to chemical formulas. Anticipation rejections are not proper for chemical formulas when the citing reference formula cannot "at once envisage" the claimed formula. Specifically, anticipation rejections are not proper when the formula includes an large number of permutations without specifically culling out a small number of variants that can be applied to the claimed subject matter.

Applying these standards to the instant case, Patent No. 5,194,581 discloses a formula that fails to meet the above recited standards. For example, R_1 is, according to the '581 specification,

alkyl, halogen, nitro, hydroxyl, amino, carboxyl, alkoxy, or combinations thereof. In other words, R₁ is one of an infinite number of combinations that encompass the vast majority of all organic moieties.

The claimed variants must be immediately envisaged for the anticipation to be proper. The '581 formula cannot lead an artisan to immediately envisage the claimed compounds, in part, because there are so many variables at play that one must first identify if the one of the '581 R' groups (of which there are 11 moieties) match the claimed structure, followed by determination of whether the R group (of which there are 9 moieties) matches the corresponding structure for the claimed compounds, followed by a determination of whether the R₁ group matches the claimed structure and deciding whether the variants (for example those of Fig. 3) fall under the "combinations thereof" rubric of the infinitely broad 'R' group recitation. In short, the '581 structures do not enable one to "at once envisage" the claimed compositions.

In fact, it took me, a practitioner with skill in the art, greater than 10 minutes to sort through the various permutations in the first office action citing the '581 case to determine whether the claimed compounds fell under the '581 patent, hardly the sort of "at once envisaged" contemplated in the MPEP.

For these reasons, the Applicants respectfully ask the Examiner to withdraw his anticipation rejection and issue a Notice of Allowance.

B. Obviousness Rejection

To properly make an obviousness rejection under *KSR*, the current authority on matters of obviousness must square with the Supreme Court's recent decision in *KSR Int'l v. Teleflex, Inc.*, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007). Accordingly, although the teaching, suggestion, motivation test is still recognized under *KSR*, the test is largely subsumed by the more general principles laid out in *KSR*. Indeed, in any given application, the combination of elements "must do more than yield a predictable result." *Id.* at 1740. Nevertheless, combining elements "in an unexpected and fruitful manner" is sufficient to render an invention non-obvious. *Id.* In fact, to properly reject an application for obviousness, there must be a reasonable expectation of success. MPEP § 2143.02.

In the analysis of whether a reasonable expectation of success exists in a given invention, the Federal Circuit stated “obviousness does not require absolute predictability of success . . . [a]ll that is required is a reasonable expectation of success.” *In re O’Farrell*, 853 F.2d 894, 903-04; 7 U.S.P.Q.2d 1673 (Fed. Cir. 1988). Thus, if a reasonable expectation of success is derived from a reference or combination of references, an invention may be rendered obvious. Conversely, where no reasonable expectation of success is derived, an obviousness rejection is improper. *Id.*

More specifically, O’Farrell provides general guidance as to when an invention falls under the reasonable expectation of success rubric, which was subsequently reaffirmed by the Federal Circuit post-KSR in *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1364; 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007). According to the Federal Circuit, “an invention would not be invalid for obviousness if the inventor would have been motivated ‘to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.’” *Id.* at 1364, quoting *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165, 77 U.S.P.Q.2d 1865 (Fed. Cir. 2006) (emphasis added).

In a secondary test posited by the Federal Circuit in *Pharmastem*, the court stated “[l]ikewise, an invention would not be deemed obvious if all that was suggested ‘was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.’” *Id.*, quoting *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165, 77 U.S.P.Q.2d 1865 (Fed. Cir. 2006) (emphasis added).

Here, no reasonable expectation of success is argued or presented by the Examiner. In fact, there is no reasonable expectation of success. The ‘581 patent presents an infinite number of combinations that can be used as substituents, which would require great variation in the “parameters or choices” to arrive at a successful result. The Examiner, in his *prima facie* case must articulate where in the prior art the parameters which are critical to the claimed invention or which choices are likely to lead to the claimed invention.

In fact, the Applicants respectfully submit that no such evidence is articulated in the ‘581 patent for the Examiner to rely on. The reason is that the structures of the present disclosure were

found to have unexpected benefits, particularly in binding DNA, over that of the '581 patent. Here, the molecules were unexpectedly found to be effective in delivering DNA to target cells. (see paragraphs 0069-0071.

Moreover, here the '581 patent only gives the most general of guidance with respect to the specific targeting of cells for delivery of molecules. The problem addressed by '581 was the creation of a delivery vehicle that was biodegradable. Here, the next generation is presented, where the delivery vehicles are those designed to be effective in targeting specific cells.

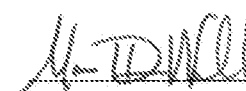
In summary, the '581 must pave the way for a reasonable expectation of success. According to the standards of the Federal Circuit to which the patent office and applicants are bound, the instant invention, while related, is not rendered obvious because no reasonable expectation of success is imparted by '581 merely by citing an nearly infinite litany of possible combinations without guidance with respect to critical parameters or direction to arrive at the claimed result.

If further issues exist that need to be resolved, the Applicants request an interview to discuss and resolve these issues.

The Director is authorized to charge any additional fee(s) or any underpayment of fee(s), or to credit any overpayments to **Deposit Account Number 50-2638**. Please ensure that Attorney Docket Number 101568.010100 is referred to when charging any payments or credits for this case.

Respectfully submitted,

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Marlan D. Walker
Reg. No. 56,928

Customer Number 33717
GREENBERG TRAURIG, LLP
2450 Colorado Avenue, Suite 400E
Santa Monica, CA 90404
Phone: (310) 586-7700
Fax: (310) 586-7800
E-mail: WalkerM@gflaw.com